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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,427

04/03/2006

Hans Haindl

2565/145

7575

26646

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05/12/2008

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EXAMINER

OSINSKI, BRADLEY JAMES

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

05/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,427	Applicant(s) HAINDL ET AL.	
	Examiner BRADLEY J. OSINSKI	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4-3-2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "40" has been used to designate both holes (page 7) and clamping ridges (page 8). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 42. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top

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margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR

1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 34-39, 41-50, 53-62 and 66-68 are rejected under 35

U.S.C. 102(b) as being anticipated by Tucker (5,718,682).

a. Regarding claim 34, Tucker discloses a chamber 34 for receiving active substances and that is arranged in a housing 42 and closed by a piercable membrane (septum) 44. Also disclosed is a connecting piece 60 which is capable of connecting to a catheter and is in fluid communicating with chamber 34. Finally, Tucker discloses clamping jaws 56a and 56b which connect to the housing as in figure 5. The clamping jaws are opposite one another. In a first position (figure 6) the clamps are laterally spaced from the housing 54 and moves to a second position (figure 5) where clamps 56 are capable of fixing a catheter between the clamping faces 64 depending on how the catheter is arranged along tube 60.

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- b. Regarding claim 35, Tucker discloses the housing and ring halves are made of a plastic material (Col.4 lines 35-40) such as polyethersulfone (Col.2 lines 56-58). Polyethersulfone is a resilient plastic as explained in other patents or publications such as Blake (2006/0064161) and van Woesik (5,452,386)
- c. Regarding claim 36, Tucker discloses welding the parts together at their interfaces (Col.4 lines 38-41) Arms 56a and 56b fit around the sides of housing part 54 and is fastened to the second housing part 42 via welding along all interfaces, including the end opposite connecting piece 64.
- d. Regarding claim 37, Figure 3 demonstrates a view of the second position. As can be seen, clamping jaws 54 are secured to the house by latching into grooves on both parts of the housing 42 and 54.
- e. Regarding claim 38, Tucker discloses groove 66 to guide the clamping jaws and connecting piece, which are integral with one another.
- f. Regarding claim 39, Tucker discloses an alternative embodiment in figure 2 in which the lower opening 22 in housing 12 acts as a guide groove which has steps that lock latch hooks 22. Such hooks/barbs are capable of being added to the clamping jaws 56.
- g. Regarding claim 41, Tucker discloses an insert element 54 that is locked in an opening in housing portion 42 via heat welding (Col.4 lines 38-40). It is also possible to lock insert element 16 to housing portion 12 via barbs 26. Furthermore from the difference between figures 3 and 4, it

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is apparent the insert element exerts pressure on the membrane 44 as the membrane's edges are squeezed in figure 3.

h. Regarding claims 42-44, Tucker discloses ridges 22 that may fit inside indentation rings to form a bayonet connection.

i. Regarding claims 45-47, As can be seen in figure 3, mutually aligning holes are provided in the housing via 66, insert element 45 at 62 and in the clamping jaws at 64. Cannula 60 progresses through all three holes.

j. Regarding claim 48, Since the lateral undercut proceeds all the way around the insert element and housing, a segment of the lateral undercut and mutually aligning holes are diametrically opposite one another.

k. Regarding claims 49 and 50, Tucker discloses that the insert element (cup) is preferably welded to the housing (Col.2 lines 24-26). As the insert element and housing are adhered together, they are adhesively-bound.

l. Regarding claim 53, Tucker discloses a chamber 34 for receiving active substances and that is arranged in a housing 42 and closed by a piercable membrane (septum) 44. Also disclosed is a connecting piece 60 which is capable of connecting to a catheter and is in fluid communicating with chamber 34. Finally, Tucker discloses an insert element 46 that is locked in an opening in housing portion 42 via welding (See claim 49 above) As can be seen from the differences between figures 3 and 4, the

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membrane 44 is clamped around its edges such that the insert element is applying pressure on the membrane.

m. Regarding claim 54, See claim 42 above.

n. Regarding claim 55, See claim 43 above.

o. Regarding claim 56, See claim 46 above.

p. Regarding claim 57, See claim 48 above.

q. Regarding claim 58, See claim 49 above.

r. Regarding claim 59, See claim 49 above.

s. Regarding claim 60, Tucker discloses a chamber 34 for receiving active substances and that is arranged in a housing 42 and closed by a piercable membrane (septum) 44. The membrane is exposed on the top side of the device as seen in figure 3 and an underside opposite the membrane. Also disclosed is a connecting piece 60 which is capable of connecting to a catheter and is in fluid communicating with chamber 34. Finally, Tucker discloses ledge 50 which is part of the housing 42, the entire housing 42 may be considered a projecting step as it is on the upper side of the port and has certain parts between the membrane 44 and connecting piece 60.

t. Regarding claim 61, See claim 34 above.

u. Regarding claim 62, Projecting step 42 is located on the clamping jaws 56.

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- v. Regarding claims 66-68, as the projecting step 42 is circular, at the point where the projecting step intersects the line described in the claim, the projecting step will be perpendicular.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 4. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker (5,718,682) as applied to claim 34 above, and further in view of Dillon et al (6,165,157).

- w. Regarding claim 40, While Tucker substantially discloses the apparatus as claimed, it does not disclose spigots and holes that are associated with one another and engage. However, Dillon et al provides spigots 66 and holes 68 in figure 4 to bind the two sides of the needle guard to each other, so that the needle guard does not fall off of the catheter 12. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide spigots and holes as taught by Dillon et al to the clamping jaws of Tucker as such is a known method of securing two pieces together that encircle another piece,

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additionally, the holes and spigots would assist in lining up the clamping jaws and binding the clamping jaws together more firmly.

5. Claims 51, 52 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker (5,718,682) as applied to claims 34, 48, 60, 61 or 62 above, and further in view of Felix et al (5,167,638).

x. Regarding claims 51, 52 and 60-62, While Tucker substantially discloses the apparatus as claimed, it does not disclose the way in which the port is made. However, Felix et al teaches injection molded plastic base (Col.2 lines 55-57) for a subcutaneous port. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the base of Tucker via injection molding as taught by Felix et al as such is a known technique of forming plastics into appropriate shapes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767